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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,297	11/02/2001	Jeff G. Hall	FORS-06675	1030

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EXAMINER

LU, FRANK WEI MIN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/033,297	<b>Applicant(s)</b> HALL ET AL.	
	<b>Examiner</b> Frank W Lu	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35,47 and 62-84 is/are pending in the application.
- 4a) Of the above claim(s) 64,69,70,72 and 74-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35,47,62,63,65-68,71,73 and 78-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election of Species*

1. Applicant's election with traverse of species (1) (claims 63, 64, and 66), (5) (claims 78-80), and (6) (claims 73, 76, and 77) in the reply filed on October 7, 2005 is acknowledged. The traversal is on the ground(s) that “[A]pplicants respectfully traverse the Examiner's assertion that Species 6, 7 and 8 represent distinct species. For claims to be restricted to different species, they must be mutually exclusive. MPEP 806.04(f). Species are always specifically different embodiments. MPEP 806.04 (f). This is not the case here. The claimed method can be configured such that all three of conditions recited by these alleged species are satisfied by a single embodiment. By way of example, and not limiting the claims to any particular embodiments, an embodiment of the method according to Claim 75, using 1X concentration of target nucleic acid, 2X concentration of second nucleic acid molecule, and 3X concentration of first nucleic acid molecule provides all of the elements of alleged species 6, 7, and 8”.

The above arguments have been fully considered and have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that species 6, 7, and 8 will be examined together. First, since claim 73 requires that said first nucleic acid molecule is in concentration excess compared to said target nucleic acid, claim 74 requires that said second nucleic acid molecule is in concentration excess compared to said target nucleic acid, and claim 75 requires that said first nucleic acid molecule is in concentration excess compared to said duplex, and these species are directed to different embodiments and species 6, 7, and 8 are mutually exclusive. Second, according to MPEP § 809.02(a), “[S]hould applicant traverse on the ground that the species are not patentably distinct,

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applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention". However, applicant does not submit evidence or identify such evidence showing the species (6) are obvious variants of species (7) and (8). Therefore, the requirement is still deemed proper and is therefore made FINAL. Since, in the amendment filed on October 7, 2005, claim 76 now is dependent on claim 75 which is a nonelected species, claims 76 and 77 are nonelected claims and claims 35, 47, 62, 63, 65-68, 71, 73, and 78-84 will be examined.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. New Matter

Claims 35, 47, 62, 63, 65-68, 71, 73, and 78-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation "the signal accumulates exponentially over time, wherein said exponential accumulation of signal over time is indicative of the presence of said target nucleic acid" is

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added into step c) of independent claim 35 and “cleaving said second cleavage structure with a cleavage agent so as to generate a detectable signal, wherein said detectable signal accumulates at an exponential rate over time, and wherein the accumulation of said detectable signal at an exponential rate over time indicates the presence of said target nucleic acid in said sample” is in step c) of newly added independent claim 62. Although the specification describes a formula for simple invasive cleavage reaction (e.g., see page 112, last paragraph bridging to page 113, first paragraph) and describes the accumulation of the ultimate product at an exponential rate (e.g., see page 117, last paragraph bridging to page 118, first paragraph), the specification fails to define or provide any disclosure to support “exponential accumulation of signal over time” recited in step c) of claims 35 and 62 because the accumulation of the ultimate product at an exponential rate does not necessarily lead to exponential accumulation of signal over time. Furthermore, page 13, lines 6-10 and page 66, lines 3-25 of the specification as suggested by applicant do not describe detecting said detectable signal comprises detection of charge as recited in claim 66.

MPEP 2163.06 notes “If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.” (emphasis added).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 35, 47, 62, 63, 65-68, 71, 73, and 78-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 35 is rejected as vague and indefinite in view of step a) because it is unclear how a second cleavage structure comprising a second probe oligonucleotide can be formed without a step that hybridizes the second probe oligonucleotide to said cleaved unpaired region since “wherein” phrases in step a) can not be considered as a method step. Please clarify.

7. Claim 62 is rejected as vague and indefinite in view of step b) because it is unclear how a second cleavage structure comprising a probe oligonucleotide can be formed without a step that hybridizes the probe oligonucleotide to said non-target cleaved product. Please clarify.

8. Claim 83 is rejected as vague and indefinite because it is unclear what means an archaeal FEN-1. Does archaeal FEN-1 mean a FEN-1 from archaebacteria? Please clarify.

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 35 and 47 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30



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(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571)272-0745.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.



Frank Lu  
Primary Examiner  
December 20, 2005